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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,818	01/16/2002	Oscar Jimenez	84167	6032

7590 04/06/2004  
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/051,818

Applicant(s)

HIROMI NAMBU

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 02 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 3, 8 and 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-7, 9-13 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 01/02/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Examiner acknowledges receipt of IDS, corrected drawings, request for extension of time and amendment filed 01/07/04. Claims 1-17 are pending. Claims 3, 8 and 14-16 are withdrawn from consideration.

Applicants traverse Examiners position that dye and antibiotic are not elected and therefore, the claims that are directed to dye or antibiotic were not considered. Applicants' traversal is on the grounds that a composition containing an active agent where the active agent is heparin or dye or antibiotic is the subject matter and that once a generic claim directed to heparin is found allowable, applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. While this is correct, it is respectfully noted that a search for a composition comprising heparin is not necessarily a search for a composition containing a dye or antibiotic. The argument is not persuasive and claims that are directed to non-elected species are withdrawn from consideration. However, claims to dye are examined. Thus claims 1, 2, 4-7, 9-13 and 17 are examined.

### ***Drawings***

The corrected drawings filed 01/07/2004 are accepted.

### ***Claim Rejections - 35 USC § 112***

1. The rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn because the claim is amended to remove the term "specific." Although, applicants argue that the term "specific" properly defines dendrimers because of the

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teaching of dendrimers such as PAPAM or polyamidoamine or polypropylene imine or POPAM or PPI in the prior art and to that end applicants submitted prior art references to show that PAPAM or polyamidoamine or polypropylene imine or POPAM or PPI are known before the instant application was filed. This argument is not persuasive because the disclosure fails to specifically indicate which dendrimer is specific and it is thus left for speculation as to which of the dendrimers is specific. It is also noted that issue regarding the term "specific dendrimers" is rendered moot by the amendment.

2. Applicant's arguments with respect to claims 1, 2, 5-7, 10-13 and 17 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 4, 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Brabander-van den Berg et al. (US 5,998,565).

de Brabander-van den Berg discloses a composition comprising polyamidoamine dendrimers (column 3, lines 5-14) and additives where the additives are poly-urethanes or polyvinylpyrrolidone (column 4, lines 31 and 32), dye or antioxidant (column 5, lines 28-61) and polyurethanes (column 6, line 27). Regarding the colloidal nature of the polyurethane, de Brabander-van den Berg does not exclude colloidal polyurethane. The ability of the instant

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composition 1 to load an active agent is a property of the composition and would be inherent to the composition of the prior art.

de Brabander-van den Berg discloses the instant composition but is silent on whether the polyvinylpyrrolidone is an aqueous dilution. However, de Brabander-van den Berg discloses that polyvinylpyrrolidone is a compound that is used to attach polar groups to the dendrimer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use polyvinylpyrrolidone to attach polar groups to the dendrimer. One having ordinary skill in the art would have been motivated to use an aqueous dilution of polyvinylpyrrolidone with the expectation that the aqueous dilution would be effective in attaching polar group to the dendrimer.

5. Claims 1, 4, 5 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froehling et al. (US 6,232,379).

Froehling discloses a composition that comprises a polyamidoamine dendrimer (column 4, line 8), polyurethane or polyvinylpyrrolidone (column 3, lines 29-35) and dyes (column 4, lines 23 and 24). Regarding the colloidal nature of the polyurethane, Froehling does not exclude colloidal polyurethane. The ability of the instant composition 1 to load an active agent is a property of the composition and would be inherent to the composition of the prior art.

Froehling discloses the instant composition but is silent on whether the polyvinylpyrrolidone is an aqueous dilution. However, Froehling discloses that polyvinylpyrrolidone modifies the dendrimer and disclosed no specific medium for the modifying agents, which in essence does not rule out aqueous dilution of the modifying agents; and there is no demonstration in applicants' specification that an aqueous dilution of

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polyvinylpyrrolidone provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use polyvinylpyrrolidone to modify the dendrimer according to the teaching of Froehling. One having ordinary skill in the art would have been motivated to use an aqueous dilution of polyvinylpyrrolidone with the expectation that the aqueous dilution would be effective in modifying the dendrimer.

6. Claims 1, 2, 5-7, 10-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhong (US 5,869,127) and Karimi et al. (EP 0 496 305) in view of Barry et al. (US 6,663,606).

Zhong discloses a method of coating a substrate with a continuous bioactive surface coating (abstract); the substrate to be coated can be a catheter (column 3, lines 65) and the bioactive agent heparin or sodium heparin (column 7, lines 49, examples 1 and 8). The coating composition also contains polyurethane; and Zhong discloses coating the substrate by dipping the substrate in the coating compositions followed by air-drying (examples 1 and 8).

Karimi discloses a composition that comprises a mixture of polyvinylpyrrolidone and polyurethane for coating surfaces such as catheter to make the surface lubricious such that when the medical instrument, in this case, catheter is inserted into the patient in need thereof, the lubricious surface contributes to patient comfort (page 2, lines 1-11).

A combined teaching of Zhong and Karimi would be a catheter coated with a composition that comprises polyurethane, polyvinylpyrrolidone and heparin or sodium heparin. However, the combined teaching of Zhong and Karimi failed to teach a composition that comprises polyurethane, heparin or sodium heparin and dendrimers or dendritic polymers and polyvinylpyrrolidone.

But Barry discloses treating the surface of catheter (column 5, line 5) with heparin (column 6, line 66) or polyvinylpyrrolidone (column 6, line 67) or polyamidoamine dendrimers (column 7, line 2). This disclosure indicates that polyamidoamine dendrimer, polyvinylpyrrolidone and heparin have equivalent efficacy in preventing substantial reduction in the pharmaceutical efficacy of pharmaceutically active material carried by the catheter.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat a catheter with the combined compositions of Zhong and Karimi where the coating composition comprises polyurethane, heparin or sodium heparin and polyvinylpyrrolidone. One having ordinary skill in the art would have been motivated to modify the combined catheter coating composition of Zhong and Karimi by including dendrimer in the composition combined composition with the expectation that the heparin and dendrimer would synergistically prevent reduction in pharmaceutical efficacy of the catheter.


7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 242-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Blessing Fubara  
Patent Examiner  
Tech. Center